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SPECIFICATION FOR ALGINATE DENTAL IMPRESSION MATERIALS

(First Revision)

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
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Indian Standard

SPECIFICATION FOR ALGINATE DENTAL IMPRESSION MATERIALS

(First Revision)

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Indian Standard

SPECIFICATION FOR ALGINATE DENTAL IMPRESSION MATERIALS

(First Revision)

0. FOREWORD

0.1 This Indian Standard was adopted by the Bureau of Indian Standards on 31 August 1987, after the draft finalized by the Dental Materials Sectional Committee had been approved by the Chemical Division Council.

0.2 This standard was first published in 1970 with considerable assistance obtained from Draft ISO Recommendation No. 1563 prepared by the Technical Committee, TC 106 of the International Organization for Standardization: which has now been finally issued as IS0 1563-1978 Alginate dental impression material. The committee, therefore, decided to revise it to align it with this IS0 standard.

0.3 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes the requirements and the methods of sampling and test for dental impression materials in powder form containing an alginate as the gel-forming ingredient.

---

*Rules for rounding off numerical values (*revised*).

2. CLASSIFICATION

2.1 On the basis of clinical applications, the materials shall be classified as follows:

a) *Class* A — For crown or inlay impressions,

b) Class *B* — For denture impressions, and

c) *Class C* — For study models and individual tray impressions.

2.2 On the basis of setting time, alginate impression materials shall be of the following types:

a) *Type* 1 — Fast setting, stated setting time of 3 minutes or less at 32°C,

b) *Type* 2 — Normal setting, stated setting time of more than 3 minutes and less than 5 minutes at 32°C.

3. REQUIREMENTS

3.1 Description — The ingredients shall be uniform and free from foreign materials. When used in accordance with the manufacturer's instructions accompanying the package the material shall form a smooth plastic mass suitable for taking impressions in the mouth,

3.2 **Odour and Flavour** — The material when used in accordance with the manufacturer's instructions shall not have an unpleasant odour or flavour.

3.3 **Irritation and Freedom from Toxicity** — The mixed paste shall neither cause irritation of the normal oral mucosa, nor contain poisonous ingredients in sufficient concentration to be harmful to human beings when used as directed in the manufacturer's instructions.

3.4 **Compatibility with Gypsum** — The impression material when tested as in A-2, shall impart a smooth surface to, and separate cleanly from a gypsum cast made from a trade brand of gypsum.

3.4.1 The gypsum recommended for use shall be as given below:

a) For Class A — at least two brands of alpha modified gypsum and one brand of alpha gypsum,

b) For Class B — At least one brand of alpha modified gypsum and two brands of alpha gypsum, and

c) For Class C — at least two brands of alpha gypsum.

NOTE — Alpha modified gypsum is characterised by a water/powder ratio of about 0·23. Alpha gypsum is characterised by a water/powder ratio of about 0·3. The relevant instructions for use of brands of gypsum available in the country shall be provided with the relevant instructions for use.

3.5 Mixing Time — The time of mixing, as stated in the manufacturer's directions to obtain a smooth working consistency, shall be not more than one minute.

3.6 **Setting Time** — The setting time shall be recorded from the commencement of mixing. The setting time, when tested as in A-3, shall not be less than the manufacturer's stated working time or more than 10 percent above the manufacturer's stated setting time.

3.7 **Working Time** -- The working time shall be recorded from the commencement of mixing. The working time, when tested as in A-4, shall be not less than 85 percent of the manufacturer's stated working time.

3.8 **Uniformity** — The ingredients shall not segregate after mixing. The mixed material shall be homogeneous and shall have a smooth surface, and shall be free from lumps and granules.

3.9 **Permanent Deformation** — The permanent deformation shall be not more than the relevant requirements given in Table 1 after 20·0 percent strain is applied for 5 seconds when tested in accordance with A-5.

3.10 **Compressive Strength** — The compressive strength shall be not less than 0·30 MPa when tested in accordance with A-6.

3.11 Strain **in Compression** — The strain shall be not less than 5 nor more than 20 percent between a stress of 0·01 and 0·10 MPa when tested in accordance with A-7.

3.12 Viscosity — When tested as in A-8, the mean diameter of the discs formed from the paste shall comply with the relevant requirements given in Table 1.

TABLE 1 VISCOSITY

SL No.	CHARACTERISTIC	REQUIREMENT FOR		
		Class A	Class B	Class C
(1)	(2)	(3)	(4)	(5)
i)	Viscosity diameter of disc, mm	$\geqslant 33$	27 to 36	$\leqslant 30$
ii)	Detail reproduction width of line reproduced, μm	20	50	75
iii)	Permanent deformation, percent	$\leqslant 3$	$\leqslant 5$	$\leqslant 7$

3.13 Proportioning Devices — The cups or spoons provided for proportioning the components, when used to measure powder and water in accordance with the manufacturer's instructions and test conditions described in A-9, shall provide a powder/water ratio which does not deviate more than 7·5 percent from the stated powder/water ratio.

4. PACKAGING AND MARKING

4.1 Packaging — The material shall be supplied in sealed air-tight containers which shall neither contaminate nor permit contamination of the contents.

4.1.1 *Instructions for Use* — Instruction for use shall accompany each package and the following information shall be included:

a) The range of mixing water temperatures (or arnbient conditions) over which the material offers adequate results;

b) The amount of powder, expressed in grams, and the amount of water, expressed in grams or millilitres, to be used for mixing;

c) The mixing time, expressed in minutes or seconds;

d) The working time available, stated for temperature increments of 2°C over the entire temperature range [4.1.1 (a)];

e) The setting time, stated for temperature increments of 2°C over the entire temperature range [4.1.1 (a)]; and

f) The latest time at which the impression mould should be poured with gypsum, for each condition of storage recommended for the impression.

4 1.1.1 *Special treatment* — Any special treatment required for the impression, such as the use of a fixative solution, during the interval of time between withdrawal from the mouth and the preparation of the gypsum.

4.1.2 *Freedom from Toxicity* — A certificate of freedom from toxicity furnished by the manufacturer, applicable to the contents, shall accompany each package (see 3.3).

4.2 Marking — Each container shall be marked with the following information:

a) Name of the material, class and type;

b) Net mass of the contents in g,

c) Number of impressions (classes B and C) or the number of partial impressions (Class A) which can be prepared from the contents,

d) Month and year of manufacture;

e) Lot number in code or otherwise to enable a batch of manufacture to be traced from records; and

f) Condition of storage, if any.

4.2.1 The containers may also be marked with the Standard Mark.

NOTE — The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. BIS marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers, may be obtained from the Bureau of Indian Standards.

5. SAMPLING

5.1 The method of preparation of samples and the criteria for conformity shall be as given in Appendix A or as agreed to between the parties concerned.

APPENDIX A

(*Clauses* 3.4, 3.6, 3.7, 3.9, 3.10, 3.11, 3.12 and 3.13)

METHODS OF TEST FOR ALGINATE IMPRESSION MATERIALS

A-I. PREPARATION OF TEST SPECIMENS

A-l.1 Prepare specimens by mixing the alginate material with distilled or deionized water using the ratio of components and the method of mixing stated in the manufacturer's instructions. Mix the alginate and water for 60 s, or the manufacturer's maximum stated mixing time if the latter is less than **60 s.**

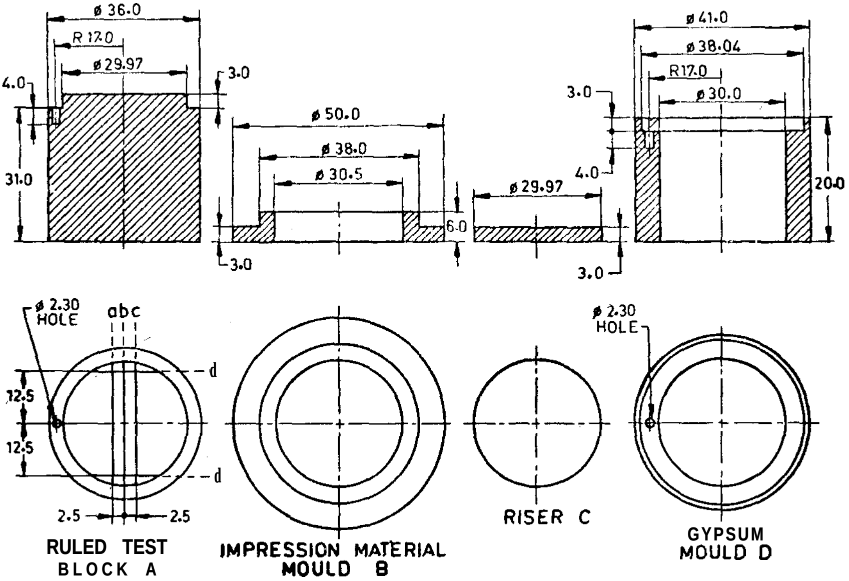
A-1.1.1 Condition the components and the test equipment for not less than 10 h and, unless stated otherwise, carry out all tests at 27 ± 2°C and 65 ± 5 percent relative humidity.

A-2. TEST FOR COMPATIBILITY WITH GYPSUM

A-2.1 Apparatus

A-2.1.1 ***Ruled Test Block A and Moulds B and D* — as illustrated in Fig 1. A rubber ring, 20 mm high and 38 mm in diameter, tightly fitting on mould B, may be used instead of mould D.**

NOTE-**Riser** C of Fig. 1 is not used, as the change in dimension is not determined.



Specifications

Materials

Ruled Block :

Austenitic steel for castings

Impression material mould:

Austenitic stainless free-cutting steel

All other parts :

Brass

Surface finish

Ruled Surface : 0·1 μ m *Ra Max*, scratch-free

All other surfaces: 0·4 μm *Ra Max*, unless otherwise specified

Tolerances : 0’1 mm to one decimal place

Ruled Test Block A

*Ruled line widths** (μ m)

Line a : 50 ± 8

Line *b* : 20 ± 4

Line *c* : 75 ± 8

Line d : 75 ± 8

*All lines have 90’ included angle.

All dimensions in millimetres.

FIG. 1 RULED TEST BLOCK FOR DETERMINING COMPATIABILITY WITH GYPSUM AND DETAIL REPRODUCTION

A-2.1.2 Flat metal or glass plate covered with cotton-backed surgical adhesive tape, sufficiently large to be a base for mould ***B***.

A-2.1.3 ***Load of*** 1 kg ***Mass***

A-2.1.4 ***Water Bath*** — capable of being maintained at 32 ± **1°C.**

A-2.2 Procedure — Place mould ***B*** on the plate covered with cotton-backed surgical adhesive tape, and slightly overfill with mixed alginate material. Thirty seconds before the working time, determined in accordance with A-3, centre the clean test block above mould ***B*** and press it down into the mass of alginate. If the alginate adheres to the surface of the ruled test block, dust the block with talcum prior to use and blow away any excess powder. Immediately place the assembly in a water bath maintained at 32 ± 1°C and load with 1 kg mass. Three minutes after the setting time, determined in accordance with A-4 or the stated setting time, whichever is greater, remove the assembly from the water bath and separate the mould, together with the plate, from the test block. Prepare a gypsum slurry, using a brand mentioned in the manufacturer's instructions, according to the directions for the product. Rinse the alginate surface with water or treat in any other way described in the manufacturer's instructions (for example, with fixative solution), and shake off the excess fluid. Place mould ***D*** on mould ***B*** and fill with the gypsum slurry, using mechanical vibration in such a way that the gypsum displaces any adhering moisture from the surface of the alginate. Allow the gypsum slurry to harden for 30 min. Separate mould ***D*** containing the gypsum cast from mould ***B*** containing the alginate material. Observe the gypsum cast under low angle illumination, with a magnification of 6 to 12 X, and record the finest line reproduced over the full length of 25 mm.

A-2.4 **Expression of Results** — Record the width of the finest line reproduced at least twice by the casts, resulting from three tests, as the test result for compatibility-detail reproduction.

A-3. DETERMINATION OF SETTING TIME

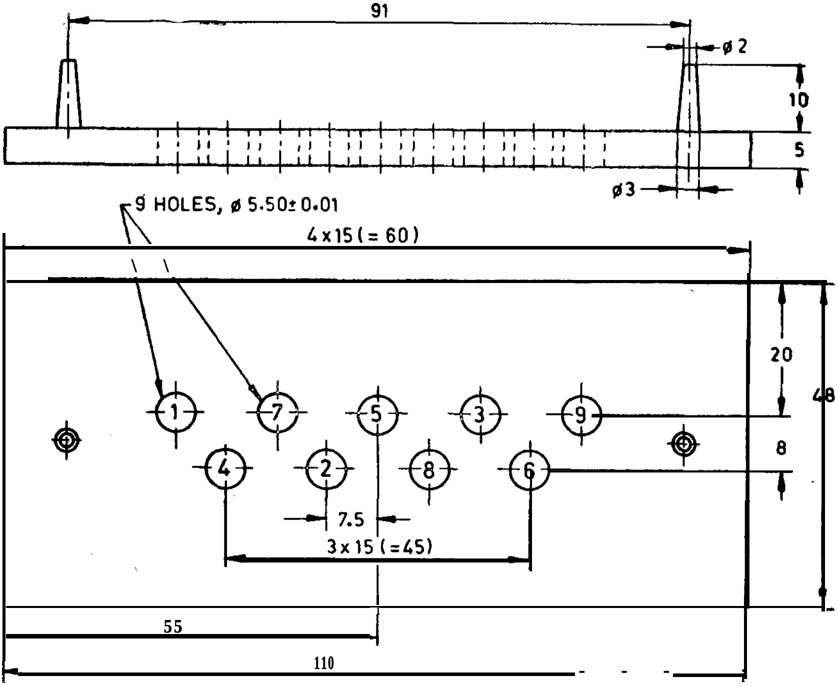
A-3.1 **Apparatus**

A-3.1.1 Flat metal plate with holes of 5·50 mm diameter, all illustrated in Fig, 2.

A-3.1.2 Steel balls having a diameter of 6·35 mm.

A-3.1.3 Metal tray, as illustrated in Fig. 3, with inside dimensions of 80 mm x 24 mm and 10·0 mm deep.

A-3.1.4 Plunger as illustrated in Fig. 4. The length of the reduced diameter portion of the plunger shall be 0·40 mm more than the thickness of the plate (*see* A-4.1).



Materials :

Plate — Brass

Leading pins — Stainless steel

All dimensions in millimetres.

Fro. 2 COMPONENT OF APPARATUS FOR DETERMINATION OF SETTING TIME — METAL PLATE CONTAINING HOLES

A-3.1.5 Dial gauge equipped with a fixed base, as illustrated in Fig. 5. The force exerted by the dial indicator shall be 0·6 ± 0·1 N (60 ± 10 gf). The foot of the dial gauge shall be a cylinder with a diameter of 4 mm and a height of at least 6 mm.

A-3.2 **Procedure** — Place the steel balls on the holes in the flat plate. Mix a double quantity of alginate material and slightly overfill the metal tray. Place the tray in the inverted position over the balls and press firmly onto the plate. Thirty seconds after the end of mixing, place the tray, plate and steel balls assembly, without disturbing the relative or overall positions of the components in a water bath at 32 ± 1°C. At the working time, as determined according to A-4, invert the tray and plate assembly so that the plate is on top of the tray. Thirty seconds before the stated setting time or as soon as possible if the period between the working time and the stated setting time is less than 30s, press the ball under hole No. 1 into the alginate for a distance of 2·0 mm by forcing the plunger into hole No. 1 until the shoulder of the plunger contacts the plate. Keep the plunger in this position for 5 ±0·5 s.

At 15 s intervals, press four further balls sequentially 2 mm into the alginate for 5±0·5s, utilizing holes number 2 to 5. Press the remaining balls (holes number 6 to 9) into the alginate at 30 s intervals for a period of 5 ±0·5 s. Transfer the assembly from the water bath and determine the permanent vertical displacement of the balls by lowering the foot of the dial gauge through the holes onto the surface of the balls. Take each reading for displacement 10 s after the positioning of the dial gauge. Plot the values obtained for the permanent vertical displacement (*see* Note) of the balls against time on Cartesian graph paper and draw the best curve through or near the points plotted. Draw, parallel to the time axis, a line which intersects the displacement at a value 0·20 mm greater than the mean of the three experimental values showing the least permanent vertical displacement. Record as the setting time the time indicated by the intersection of this line with the curve.

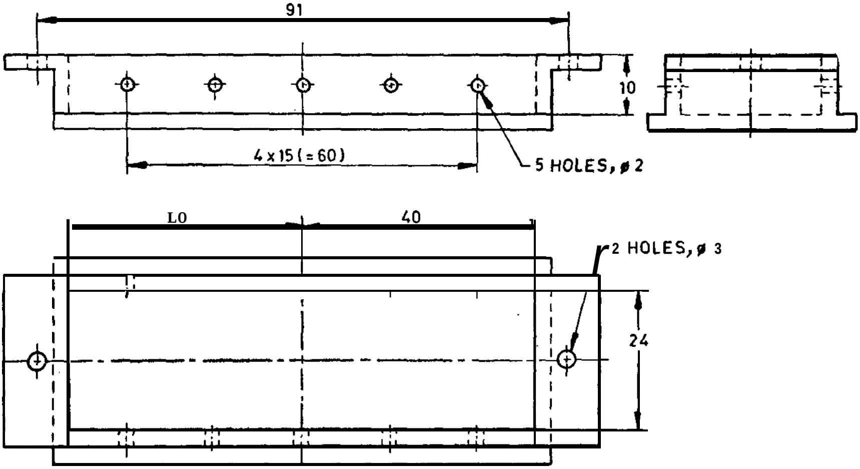
NOTE — In the early stage of setting, the 2 mm movement of the steel ball can lead to a flow of the alginate material which results in inaccurate displacement measurements. Such measurements, suggesting a high degree of elasticity of the material shall be discarded.

Carry out this procedure to determine the time of setting three time, round of the average to the nearest 15 s, and record as the test result.

A-4. DETERMINATION OF WORKING TIME

A-4.1 Apparatus

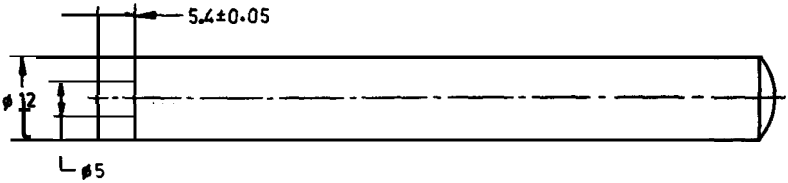
A-4.1.1 ***Loading Device*** — As shown in Fig. 6 that allows essentially frictionless movement in the vertical direction. The movable column B shall have a mass of 125 g and shall terminate in a platen (15 mm in diameter) parallel to the base of the instrument. There shall be provision for the attachment of weights to increase the mass of the movable column to 500 and 2 000 g as required for the several classes of material.



Material — Brass

All dimensions *in* millimetres.

FIG. 3 COMPONENT OF APPARATUS FOR DETERMINATION OF SETTING TIME-METAL TRAY



Material — Brass or Stainless steel

All dimensions in millimetres.

FIG. 4 COMPONENT OF APPARATUS FOR DETERMINATION OF SETTING TIME-PLUNGER

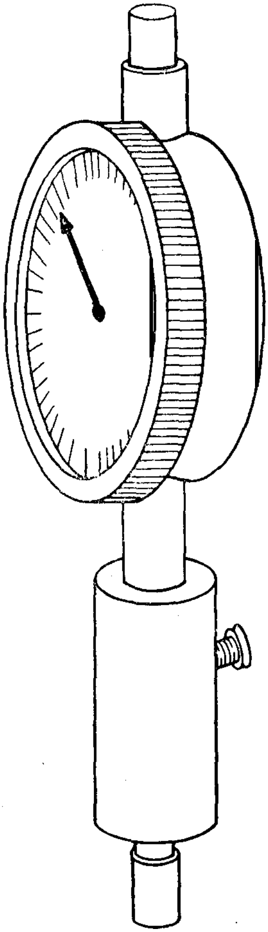


FIG. 5 COMPONENT OF APPARATUS FOR DETERMINATION OF SETTING TIME-DIAL GAUGE EQUIPPED WITH FIXED BASE

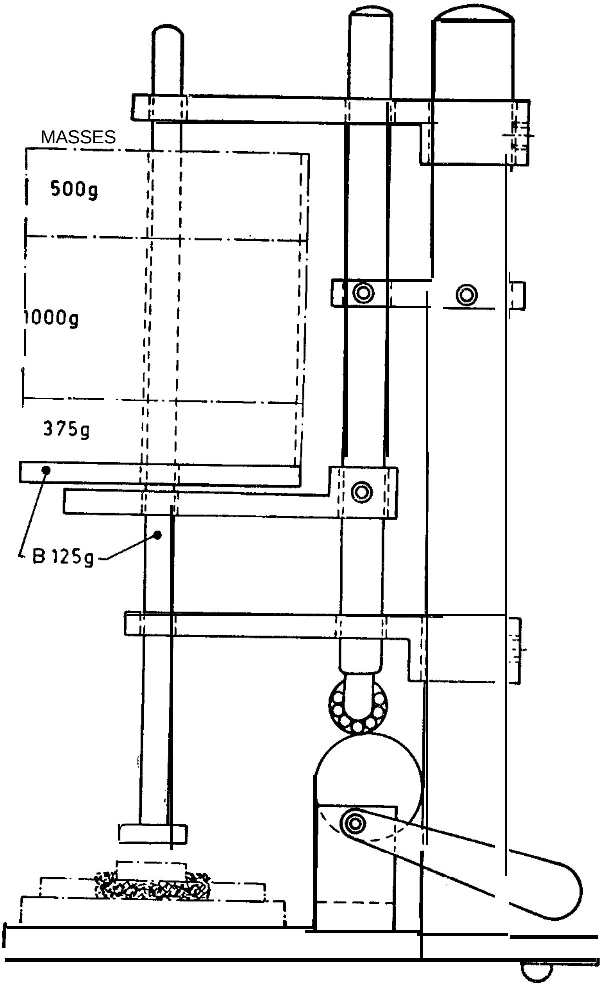


FIG. 6 APPARATUS FOR DETERMINATION OF WORKING TIME AND VISCOSITY

A-4.1.2 Mould with inside dimensions of 130 mm x 25 mm x 3 mm and a flat rectangular base of constant thickness, made, for example, of glass.

A-4.1.3 Six circular glass or polymethyl methacrylate discs 5 ± 1 mm thick and 16 ± 0·2 mm in diameter. The flat surfaces of each disc shall be parallel to within 0·01 mm.

A-4.1.4 Dial gauge, accurate to 0 01 mm, mounted perpendicularly on a stable base. The force exerted by the dial indicator shall be 0·6 ± 0·1 N (60 ± 10 gf).

A-4.2 **Procedure** — Position six circular discs on the mould assembly and place beneath the dial gauge so that the foot contacts the upper surface of the first disc. Read the dial gauge and record the value as A_1. Repeat the procedure for each of the other discs and record the value as A,, As, A_4, A_5 and A_6. Remove the discs and place in the same order as dimensions A_1 to A_6 were recorded. Fill the mould assembly with mixed alginate material and roughly level with a spatula. Then place the six discs on the alginate surface in the same order as the readings A, to A_6 were taken and in such a manner that they are equally distributed over the mould cavity. Place the entire assembly on the base of the loading device in such a position that the first disc can be forced into the alginate material by lowering the movable column. Select an appropriate weight for the movable column (125, 500 or 2 000 g) such that the thickness of the alginate layer beneath the first circular disc is between or as near as possible to 0·13 to 0·33 mm. Apply the load for 10 seconds to each of the six discs according to the following time schedule:

a) load first disc:	30 seconds after the end of mixing,
b) load second disc:	45 seconds after the end of mixing,
c) load third disc:	30 seconds before the stated -working time,
d) load fourth disc:	15 seconds before the stated working time,
e) load fifth disc:	at the stated working time, and
f) load sixth disc:	15 seconds after the stated working time.

NOTE — For very fast setting materials, load the discs at intervals of 15 seconds, starting at 30 seconds after the end of mixing.

After this loading sequence, transfer the whole assembly to the dial gauge and take readings with the foot of the dial gauge in contact with the respective circular discs. Record these values as B_1, B_2, B_3, B_4, B_5 and

B_8. The difference between the 'B' and 'A' readings, B — A, will be the thickness of the alginate beneath the circular discs, Plot the figures for the thickness of the alginate layer, B — A, under each disc. Plot the figures for the thickness of the alginate layer, against time on Cartesian graph paper and draw the best curve through or near the points. Using the curve drawn, record as the working time the first time (rounded to the nearest 5 seconds) that the thickness of the alginate layer is double the thickness of the alginate layer beneath the first disc Record the mean of three such determinations, rounded to the nearest 15 seconds as the test result.

A-5. DETERMINATION OF PERMANENT DEFORMATION AFTER 20 PERCENT STRAIN

A-5.1 Apparatus — The following apparatus, or another with equal accuracy, performance and speed, shall be used.

A-5.1.1 Dial gauge mounted on a stable base. The gauge shall terminate at its foot in a platen (15 mm diameter) parallel to the base of the device, as illustrated in Fig. 7. The force exerted by the dial gauge assembly shall be 0·6 ± 0·1 N (60 ± 10 gf).

A-5.1.2 Apparatus to apply a 20 percent strain as illustrated in Fig. 8. The distance between the adjustable Table *T* and platen *P* (parallel to the table) shall be 16·0 mm when beam *B* touches stop *S*.

A-5.1.3 Water bath, capable of being maintained at 32 ± 1°C.

A-5.2 Preparation of Test Specimens — Prepare the test specimens by placing a ring, 30 mm inside diameter and 16 mm high, on a flat glass or metal plate covered with polyethylene film, and fill slightly more than one-half full with alginate material mixed according to the manufactuer's instructions. Place a cylindrical metal mould, 12.5 mm inside diameter, 12·0 mm outside diameter and 20·0 mm high, immediately inside the ring and force the mould into alginate until the mould touches the plate and alginate has exuded up to the top of the mould. Press a second flat glass or metal plate, covered with polyethylene film, on the top of the mould. Thirty seconds after the end of mixing, place the mould and its accompanying plates in a water bath at 32 ±1 "C. At the stated setting time or at the setting time determined in accordance with A-4, whichever is greater, remove the assembly from the water bath. After removing the flash, separate the specimen from the mould and place on the base of the dial gauge.

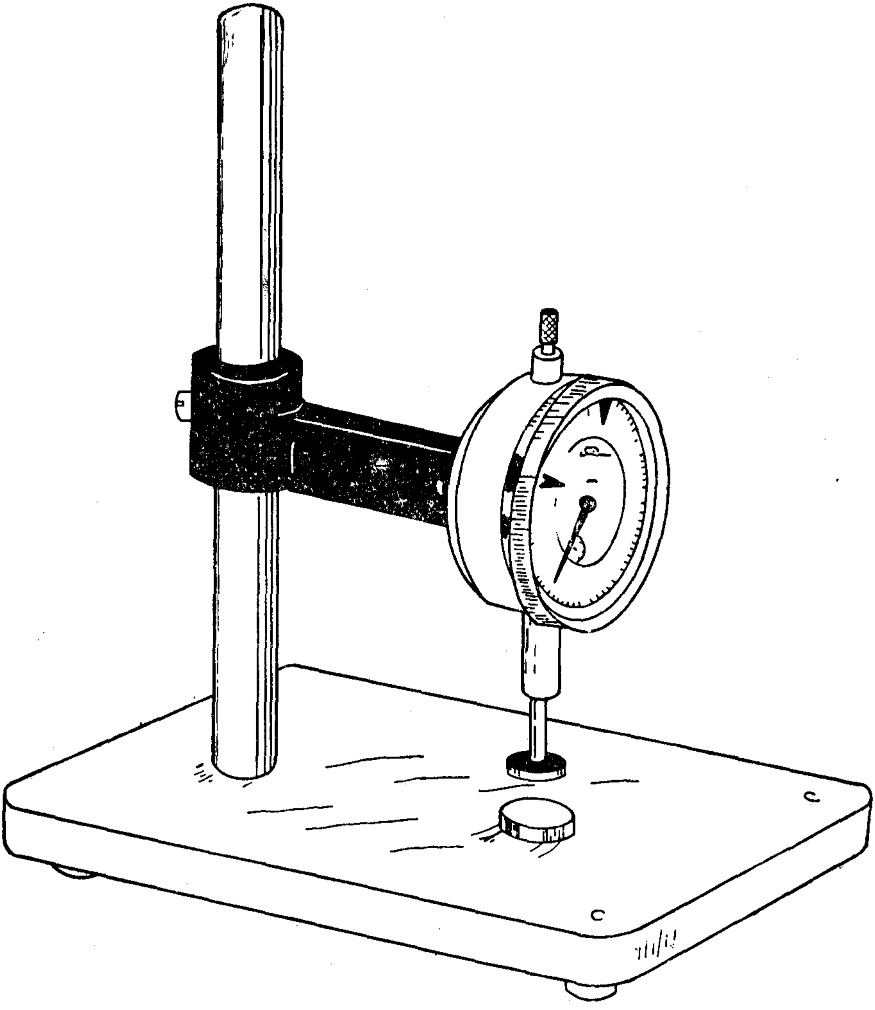


FIG. 7 INSTRUMENT FOR DETERMINING HEIGHT OF COMPRESSION SET SPECIMEN BEFORE AND AFTER STRAINING

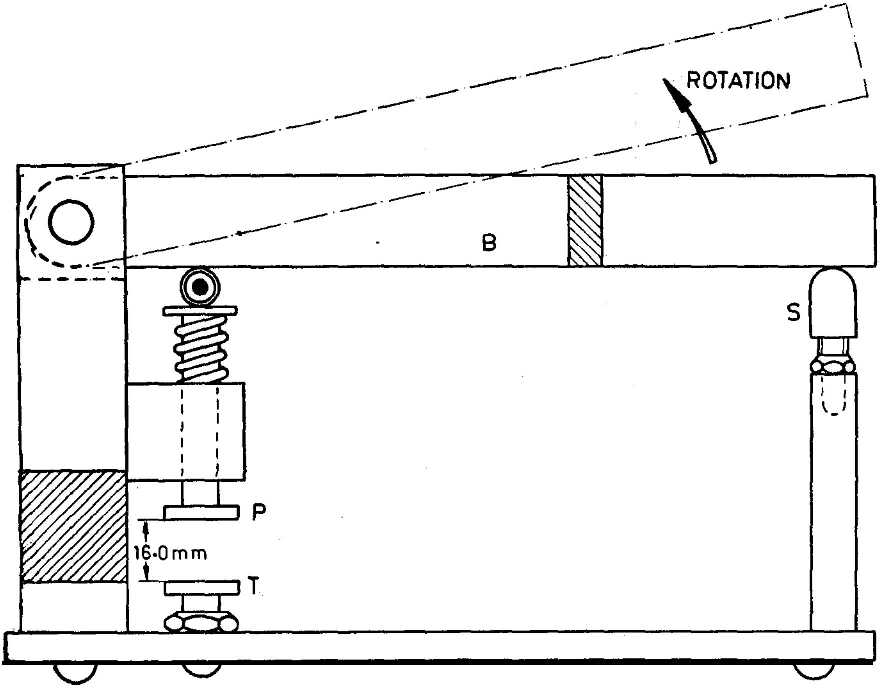


FIG. 8 APPARATUS FOR STRAINING COMPRESSION SET SPECIMEN

A-5.3 **Procedure** — Carry out the test in accordance with the time schedule detailed below, where time *S* is the manufacturer's stated setting time or the setting time determined in accordance with A-4, whichever is' the greater:

S + 45 *seconds* — Gently lower the platen of the dial gauge to contact the specimen;

S + 55 *seconds* — Read the dial indicator and record the value as reading *A;*

S + **60** *seconds* — Transfer the specimen to the strain apparatus and place upon table, *T*. Bring the beam *B* into contact with stop *S*, thereby subjecting the specimen to a 20 percent deformation and keep in this position for 5 ± 0·5 seconds;

S + 90 seconds — Gently lower the platen of the dial gauge to contact the specimen which has just before been placed upon the dial gauge base; and

S + *100 seconds* — Read the dial indicator and record and the value as reading ***B.***

A-5.4 **Expression of Results** — The permanent deformation expressed as a percentage, is given by the formula:

$$\frac{A - B}{20} \times 100$$

where 20 is the original length in millimetres of the specimen. Record the average permanent deformation of three specimens as the test result.

6. DETERMINATION OF COMPRESSIVE STRENGTH

A-6.1 **Apparatus** — Any apparatus which permits loading at a rate of 100 N/min and that is capable of measuring force with an accuracy of 0·5 N in accordance with the procedure in A-6.2 may be used.

A-6.2 **Procedure** — Sixty seconds after the stated setting time or the setting time determined in accordance with A-4, whichever is the greater, place specimen prepared as specified in A-5.2 and covered at both ends with a piece of bond paper, between the anvils of the compressive strength testing apparatus. Load the specimen continuously and as uniformly as possible to give an average rate of loading of 100 ± 20 N/min until fracture. Record the maximum applied load to the nearest 0·5 N.

A-6.3 **Expression of Results** — Calculate the compressive strength, C, in megapascals, using the formula:

$$C = \frac{4\,P}{\pi\,d^2}$$

where

P = maximum applied load, in newtons; and

d^2 = diameter, in millimetres, of the test specimen.

Record the average compressive strength of three specimens as the test result.

A-7. DETERMINATION OF STRAIN IN COMPRESSION

A-7.1 Apparatus — Any suitable instrument such as the apparatus illustrated in Fig. 9 having a dial indicator graduated in 0·01 mm, and capable of applying the force required for the test in accordance with the procedure outlined in A-7.2, may be used.

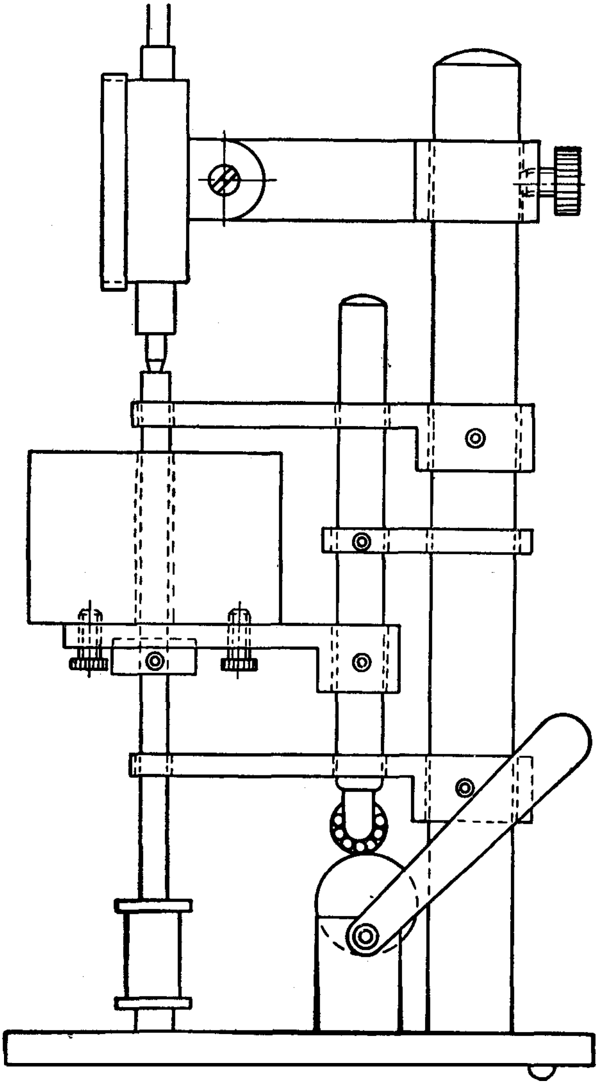


FIG. 9 APPARATUS FOR DETERMINATION OF STRAIN IN COMPRESSION

A-7.2 Procedure — Sixty seconds after the stated setting time or the setting time determined in accordance with A-4, whichever is the greater, place a specimen prepared as specified in A-5.2 in the instrument and subject it to a load of 125 ± 5 g producing a stress of 0·01 MPa. Thirty seconds later read the dial gauge. Record this value as reading C. Sixty seconds after application of the stress of 0·01 MPa, carefully apply an additional load of 1 100 ± 5 g thereby producing a total stress on the specimen of 0·1 MPa within a period of 10 seconds. Thirty seconds after initiating the increase in stress to 0·1 MPa read the dial gauge and record this value as reading *D*.

A-7.3 **Expression of Results** — The strain in compression expressed as a percentage is given by the formula:

$$\frac{C - D}{20} \times 100$$

where 20 is the original length in millimetres of the specimen.

Record the average strain of three specimens as the test result.

A-8. TEST FOR VISCOSITY

A-9.1 Apparatus

A-8.1.1 Load of 1 500 ± 2 g mass mounted in a loading device such as that shown in Fig. 6, in such a manner as to allow essentially frictionless movement of the movable column in the vertical direction. The apparatus described in **A-9.1** may be used, provided that the mass of the movable column is 1 500 g.

A-8.1.2 Glass delivery tube of approximately 10 mm internal diameter, designed to deliver 0·5 ± 0·02 ml, by means of a plunger.

A-8.1.3 Two glass plates approximately 60 mm square and of mass 20 ± 2 g each.

NOTE — During testing procedure, it is essential that the glass plates be maintained parallel and that no rotational movement be allowed to rake place.

A 8.2 **Procedure** — Using the delivery tube, dispense 0·5 ml of the mixed material onto the glass plate. Gently lower the second glass plate and the 1500 g load onto the material, 30 seconds after the end of mixing for Type 1 material and 60 seconds after the end of mixing for Type 2 material. Five seconds later, remove the load and measure the diameter of the disc of material to the nearest 0·5 mm, across two diameters at right angles to each other. Calculate the mean of these two measurements for each specimen. Record the average of three determinations as the test result for viscosity.

A-9. PROPORTIONING DEVICES

A-9.1 Weigh the amount of powder in grams, delivered using the powder proportioning device according to the manufacturer's instructions, five times and calculate the average mass. Measure the internal volume in millilitres of the water proportioning device five times and calculate the average. Record the average amount of powder in grams, divided by the 'average water content in millilitres as the test result,

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*Sales Office in Calcutta is at 5 Chowringhee Approach, P. 0. Princep Street Calcutta 700072 — 27 68 00

†Sales Office in Bombay is at Novelty Chambers, Grant Road, Bombay 400007 — 89 65 28

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